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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,727	09/30/2003	Alan Verkman	UCSF-291	2946
500	7590	11/02/2006	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC			SPIVACK, PHYLLIS G	
701 FIFTH AVE			ART UNIT	
SUITE 5400			PAPER NUMBER	
SEATTLE, WA 98104			1614	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/676,727	Applicant(s) VERKMAN ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8-14,19,44-46,50-55,59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44 and 45 is/are allowed.
- 6) ☒ Claim(s) 1-3,8-14,19,46,50-55,59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7-27-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants' Amendment filed July 27, 2006 is acknowledged. Claims 4-7, 15-18, 20-43, 47-49, 56-58 and 61-64 are canceled. Claims 1-3, 8-14, 19, 44-46, 50-55, 59 and 60 remain under consideration.

An Information Disclosure Statement filed July 27, is further acknowledged and has been reviewed.

Subsequent to various amendments to the Abstract, the objection thereto is withdrawn.

Claims 1-3, 8-14, 19, 46, 50, 51, 59 and 60 were rejected under 35 U.S.C. 112, first paragraph, in the last Office Action as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants have cited paragraphs [0045], [0053], [0055], [0061], [0085], [00101] and [00104] as providing support for the presently amended claims. A review of those citations fails to provide support for a symptom "treatable by inhibiting CFTR-mediated ion transport" in claim 1 and for the recitation "an aliphatic group" in claims 1 and 46.

New matter may not be introduced into an application after filing. *In re Rasmussen*, 211 USPQ 323.

In the last Office Action claims 1-19 and 41-43 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

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which it is most nearly connected, to practice the invention. The claims were directed to treating a cystic fibrosis transmembrane conductance regulator (CFTR) protein-mediated condition or symptom comprising administering a compound of instant formula I. The specification provides support for reducing intestinal fluid secretion in laboratory assays involving toxin-treated intestinal loops and in rat intestinal loops comprising administering a single compound, 3-[(3-trifluoromethyl)phenyl]-5-[(4-carboxyphenyl)methylene]-2-thioxo-4-thiazolidinone, referred to as CFTR_{inh}-172, which is the compound of formula Ic. The compound shows favorable antidiarrheal applications and prevents cAMP and cGMP induced ion/fluid secretion.

It was asserted the instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation.

Applicants argue the disclosure on page 24, paragraph [00104], provides enablement for the administration of the compound of formula Ic to inhibit aberrant CFTR-mediated ion transport and may be used for treating conditions and symptoms related to such aberrant ion transport such as increased intestinal secretion of fluids and diarrhea. Further, Applicants urge the specification provides support for determining which compounds inhibit CFTR-mediated ion transport in various assays, and enablement is not precluded by the necessity for some experimentation, such as routine screening.

The Examiner is in agreement that the specification provides assays to determine compounds that inhibit CFTR-mediated transport. However, given its

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broadest interpretation, claim 1 is drawn to methods of treating various pathologies, symptoms and conditions involved with the CFTR protein. A successful treatment modality for one particular type of pathology, symptom or condition involved with the CFTR protein, such as secretory diarrhea, does not presage success for treating another type.

All working examples are limited to the administration of a single compound, 3-[(3-trifluormethyl)phenyl]-5-[(4-carboxyphenyl)methylene]-2-thioxo-4-thiazolidinone, referred to as CFTR_{inh}-172. Applicants have failed to provide guidance as to which particular compound would be preferred for treating the various conditions and symptoms associated with the CFTR protein or aberrant ion transport by CFTR that are broadly encompassed in the claim language. Those disease states contemplated, other than secretory diarrhea, are absent.

Because no direction is provided to distinguish therapy among the various types of pathologies encompassed in the claim language involving the CFTR protein or aberrant ion transport by CFTR, the rejection of record under 35 U.S.C. 112, first paragraph, is maintained over claims 1, 8-14 and 19. The rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn over claims 2 and 3.

In the last Office Action claims 1-19 and 46-60 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and under 35 U.S.C. 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention. It was asserted the claims contains subject matter that was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Subsequent to the deletion of selenium for either the A₃ or A₄ terms, as well as the deletion of the recitations "an organic group", "A₄ comprises one or more carbons or heteroatoms and may be present or absent" and "a pharmaceutically acceptable derivative", the rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn.

Claims 46-60 were rejected under 35 U.S.C. 102(b) as being anticipated by Roman et al., Farmatsevtichnii Zhurnal (abstract). It was asserted Roman teaches the preparation of compounds for therapeutic application comprising 3-aryl-5-arylidene-2-thioxothiazolidine-4-ones of instant formula I.

Following a review of the translation provided by Applicants of the cited document, the rejection of record under 35 U.S.C. 102(b) is withdrawn. Roman fails to teach or suggest the 3-aryl position is a phenyl substituted with a trifluoromethyl group.

Claims 2 and 3 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within

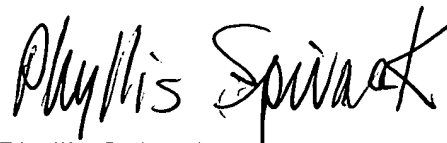
TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 27, 2006



Phyllis Spivack

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**PHYLLIS SPIVACK
PRIMARY EXAMINER**